

## **REMARKS**

Claims 1-5, 7-20, 23-37, 41, 42, and 47-52 are currently pending. Claims 6, 21, 22, 38-40 were previously cancelled and claims 43-46 are currently cancelled. Claims 37, 41 and 42 are currently withdrawn as directed to a non-elected invention. Claims 1, 19 and 47-52 are currently amended and support can be found, for example, at paragraph [0028]. No new matter is added.

### **Claim Rejection under 35 U.S.C. § 112**

Claims 1-5, 7-36 and 43-52 stand under 35 USC 112, first paragraph as allegedly failing to comply with the written description requirement. Specifically the Examiner objects to the use of the term “painful sensations.” The claims have been amended to remove this language and this rejection is believed to be moot.

### **Claim Rejections under 35 U.S.C. § 103**

Claims 1-5, 7-20, 23-36, and 43-52 stand rejected under 35 USC 103(a) as being allegedly rendered obvious by US Patent 6,066,163 to John (“John”) in view of US Patent 6,353,762 to Baudino et al. (“Baudino”). Applicants request reconsideration of this rejection. Claims 43-46 are cancelled, thus the rejection of these claims is moot.

Independent claims 1 and 19 recite “determining the patient’s threshold for pain at a first time; then providing a stimulation signal to the stimulator to stimulate the target site; determining the patient’s threshold for pain at a second time; and adjusting the stimulation signal if necessary in response to the determination of the patient’s threshold for pain at the second time in order to affect chronic pain.”

John does not disclose chronic pain or a method of treating a patient having chronic pain. John describes treatment of traumatic brain injury and the resulting persistent vegetative state. (See e.g. col. 3, lines 1-4). In order to rehabilitate the patients, a brain stimulator is implanted in a brain region of the patient and the patient is stimulated according to a set of stimulation parameters (col 3, lines 19-24). John states, “[a] present state is measured and compared to a reference state...[and if] after a specified amount of time or number of attempts, the comparison fails to meet a set of criteria then new sets of stimulation parameters are selected ” (col 3, lines 30-33). John describes that “subjective measures such as pain or discomfort” may also be used (col 9, lines 10-11). John does not specifically describe determining a patient’s *threshold for pain* at a first time and then determining a patient’s *threshold for pain* at a second time and

certainly does not describe making these determinations in a patient suffering from chronic pain (which is different than acute pain).

Baudino describes techniques for treating peripheral vascular disease. Although Baudino mentions chronic pain in column 9, there is no disclosure of any determination of a patient's threshold for pain. Baudino does state "a sensor may be included for generating a signal related to the extent of a physical condition for treating a neurological disorder or pain" (col 2, lines 57-60). However, there is no specific disclosure, motivation, teaching, or suggestion to determine a patient's pain threshold before providing a stimulation signal, determine a patient's pain threshold at a subsequent different time, and then adjust the stimulation signal in response to this determination at the subsequent different time. Thus, Baudino does not cure the above-mentioned deficiencies of John.

For at least these reasons, Applicant submits that claims 1 and 19, and the claims that depend therefrom, are not rendered obvious by John in view of Baudino. Accordingly, withdrawal of the rejection is requested.

Claims 1-5, 7-20, 23-36 and 43-52 stand rejected under 35 USC 103(a) as being allegedly rendered obvious by John in view of US Patent 5,938,690 to Law et al. ("Law") in further view of Baudino. Applicant requests reconsideration of this rejection. Claims 43-46 are cancelled, thus the rejection of these claims is moot.

Law does not cure the deficiencies of John and Baudino described above. Law does not disclose "determining the patient's threshold for pain at a second time and adjusting the stimulation signal if necessary in response to the determination of the patient's threshold for pain at the second time." Law describes a system for use with known neuromodulation systems that uses a computer database of information in connection with a pain map of an individual to assist in determining waveform and electrode configuration and lead placement. Law states that "[p]re-operatively a patient enters a pain topography which represents the patient's experienced pain" (col 3, lines 5-6). Law programs a beginning stimulation amplitude, at which setting the user defines the area of the body where the stimulation is felt. This area is then compared to the initial pain topography to determine if the proper area of the body is being stimulated. As such, Law does not describe determining the patient's threshold for pain at a second time during or

after stimulation of the target site. Additionally, Law does not disclose implanting a stimulator in a target site of the brain, but rather is directed to spinal stimulation.

For at least these reasons, Applicant submits that claims 1 and 19, and all claims that depend therefrom, are not rendered obvious by John and Law in view of Baudino. Accordingly, withdrawal of this rejection is requested.

**Conclusion**

The Office is authorized to charge the extension of time fee and any additional fees required, or credit any overpayments, to Deposit Account No. 11-0600.

The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Respectfully submitted,

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